



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Amy F. Petrik, Ph.D., 240-627-3721; amy.petrik@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows:

Newcastle Disease Virus-Like Particle Displaying Prefusion Stabilized SARS-CoV-2 Spike and Its Use

Description of Technology:

SARS-CoV-2 has resulted in a global pandemic, sparking urgent vaccine development efforts. The trimeric SARS-CoV-2 spike stabilized in its prefusion conformation by the addition of 2 proline mutations (“SARS-CoV-2 S2P”) is the antigenic basis of SARS-CoV-2 vaccines that are currently authorized for use in the United States.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) sought to optimize the presentation of SARS-CoV-2 S2P to the immune system with the goal of eliciting a strong and durable immune response. The researchers designed fusion proteins made of SARS-CoV-2 S2P and Newcastle Disease fusion transmembrane domain and cytosolic tail which form virus like particles (VLPs) displaying the SARS-CoV-2 S2P on the particle surface.

SARS-CoV-2 S2P displaying Newcastle Disease virus-like particles (“S2P-NDVLP”) elicited a robust immune response two weeks after a single immunization. The S2P-NDVLP also elicited an improved immunogenicity despite delivering a lower number of SARS-CoV-2 S2P antigens than the soluble SARS-CoV-2 S2P to which they were compared. This improved immunogenicity is likely due to several characteristics of S2P-NDVLPs such as the mass and large size of the VLP particle that can result in a strong immune response and increase uptake of the S2P by dendritic cells. Displaying multiple SARS-CoV-2 S2P on a single particle could allow multiple B-cell receptors on individual B cells to bind that single particle, thereby cross-linking the B-cell receptors and activating those B cells. Lastly, the lipid membrane of the S2P-NDVLP could allow the immunogen to more closely mimic the real virus and boost immune response.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404.

Potential Commercial Applications:

- A single dose SARS-CoV-2 vaccine

Competitive Advantages:

- S2P-NDVLP with potential to elicit higher levels of neutralizing antibodies than current vaccines with a single dose

Development Stage: Preclinical Research.

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Publications: Yang, Y *et al.*, (2021). Newcastle Disease Virus-Like Particles Displaying Prefusion-Stabilized SARS-COV-2 Spikes Elicit Potent Neutralizing Responses. *Vaccines*, 9(2), 73.

Intellectual Property: HHS Reference Number E-068-2021 includes U.S. Provisional Patent Application Number 63/140,250, filed 01/21/2021.

Licensing Contact: To license this technology, please contact Amy F. Petrik, Ph.D., 240-627-3721; amy.petrik@nih.gov.

Dated: March 24, 2021.

Surekha Vathyam,

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Technology Transfer and Intellectual Property Office,

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